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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STRZELECKA, TERESA E

ART UNIT PAPER NUMBER

1637

DATE MAILED: 08/19/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,658

Applicant(s)

BRADLEY ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 18-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with partial traverse of Group I (claims 1-17) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that Groups III and IV (claims drawn to a method of nucleic acid hybridization in the presence of antioxidants and a kit comprising labeled nucleic acids and antioxidant, respectively), and Groups V and VI (claims drawn to a method of nucleic acid hybridization under controlled humidity and a kit comprising an array in a housing, respectively), should be rejoined, since the search for methods would automatically result in search for the kits. This is not found persuasive because, for example, a kit comprising a labeled nucleic acid in a solution with an antioxidant can be used in protein-DNA binding assays, with the antioxidant being DTT, therefore search for a method of hybridization in the presence of an antioxidant would not necessarily reveal references to the kits.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 18-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 9.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

4. Claims 7-11 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 7 and 8 are indefinite because of the limitation "... a procedure comprising random priming, nick translation, amplification, or equivalent..." (emphasis added). It is unclear what is an equivalent to the three methods listed, and none were defined in the specification. It is also unclear what is a procedure which comprises all three methods.

B) Claims 7 and 8 are indefinite over the recitation of "a procedure comprising random priming, nick translation, amplification" because the claim recites an improper format for a Markush group. Claims which recite members of a Markush group must be "close-ended". This rejection may be overcome by amendment of the claim to recite "group consisting of". See MPEP 2173.05(h).

C) Claim 9 is indefinite because of the limitation "... the detectable label comprises Cy3 or Cy5 or equivalent..." (emphasis added). It is unclear what labels are equivalents of the CY3 or Cy5 labels, and no definition of the equivalents is provided in the specification.

D) Claims 10 and 11 are indefinite because of the limitation: "... DNase enzyme, or equivalent..." (emphasis added). It is unclear what is meant by an equivalent of a DNase.

E) Claim 15 is indefinite because of the limitations "... sequences representing a defined part of or substantially an entire chromosome..." (emphasis added). It is unclear what is a "defined part" of a chromosome (how is it defined) and what is a "substantially entire" chromosome.

F) Claim 16 is indefinite because of the limitation "... substantially an entire genome...". It is unclear how many sequences would be necessary to have "substantially entire" genome represented.

G) Claim 17 is indefinite because of the limitation "... the chromosomal or genome is derived from a human...". It is unclear what chromosomal part is derived from a human.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-9, 10-12, 15 and 16 rejected under 35 U.S.C. 102(b) as being anticipated by Lockhart et al. (Nature Biotechnology, vol. 14, pp. 1675-1680, 1996; cited in the IDS).

Lockhart et al. teach generating molecular profile of genomic (murine) DNA by hybridization of short (on average 50 bp) labeled fragments of target RNA or labeled cRNA to an array of 16,000 probes derived from murine mRNA. Labels were introduced by incorporation of biotin-labeled or fluorescein-labeled UTP and CTP. RNA molecules were fragmented with heat in the presence of magnesium. The stringent hybridization conditions were: temperature was 40 °C for 15 to 16 hours, the hybridization buffer contained 0.9 M NaCl, 60mM NaHPO₄, 6 mM EDTA and 0.005% Triton X-100, pH 7.6. (Abstract; Figure 1, 2, 3; page 1679; page 1677, second paragraph).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. as applied to claims 1 and 12 above, and further in view of Anderson et al. ("Nucleic Acid Hybridization", IRL Press, pp. 98-99, 1985).

A) Claim 13 is drawn to the hybridization temperature being from about 60 °C to about 65 °C.

B) The teachings of Lockhart et al. were described above. Lockhart et al. do not teach hybridization temperature of from about 60 °C to about 65°C, but they do teach very high stringency conditions, as the NaCl concentration is 0.9 M.

C) Anderson et al. teach hybridization conditions for aqueous solutions. They teach that hybridization temperature of 68 °C is used with a hybridization buffer containing 0.15 M NaCl, 20 mM Tris-HCl, 1 mM EDTA at pH 7.8 (page 98, 99).

It would have been *prima facie* obvious to one of ordinary skill in the art to have adjusted the hybridization conditions according to the ionic strength of the solution either by varying the salt concentration or temperature to achieve desired stringency of the hybridization reaction.

9. Claims 14 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al.

A) Claim 14 is drawn to a target nucleic acid consisting of DNA derived from a human, and claim 17 is drawn to human genome.

B) The teachings of Lockhart et al. were described above. Lockhart et al. do not teach hybridization of target nucleic acids derived from human genome.

It would have been *prima facie* obvious to one of ordinary skill in the art to have used the hybridization technique of Lockhart et al. for analysis of human genomic DNA, since there are no qualitative differences between murine and human DNA which would have prevented use of such methodology as applied to nucleic acids derived from human genome. The motivation to do so, expressly provided by Lockhart et al., would have been that this approach allowed simultaneous monitoring of tens of thousands of genes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
August 15, 2002

TS

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

Kenneth R. Horlick
8/15/02